

Applicants: Christophe P.G. Gerald, et al.
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REMARKS

Claims 76-77, 97-98, 107-108, 134-135, 142-145, 158, 161 and 183-191 are pending in the subject application. By this Amendment, applicants have canceled claims 76-77, 97-98, 107-108, 134-135, 142-145, 158, and 161, without disclaimer or prejudice to applicants' right to pursue this subject matter in the future; and have amended claims 183-191.

Applicants maintain that the amendments to the claims are fully supported by the specification. Support for the amendments to claims 183-191, to define mammalian NPFF receptors, may be found *inter alia* in the specification as originally filed on page 35, lines 17-29.

Applicants maintain that the amendments to claims 183-191 raise no issue of new matter, and respectfully request entry of this Amendment. Upon entry of this Amendment, claims 183-191 will be pending and under examination.

Rejection Under 35 USC §112, first paragraph

On page 3 of the October 6, 2003 Office Action, the Examiner rejected claims 183-191 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner stated that the claim(s) allegedly contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or to use the invention.

The Examiner alleged that the claims are drawn to a method of preparation of a pharmaceutical composition which is an agonist of

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a mammalian NPFF receptor. The Examiner then alleged that the method is not enabled because i) the specification is not enabled for the full scope of mammalian NPFF receptors; ii) the specification does teach how to make an agonist of the NPFF receptor; iii) the specification does not teach the nexus between the agonist and any disease state.

Applicants respectfully traverse the Examiner's rejection for the reasons set forth below.

Applicants respectfully point out that the Examiner's rejection of claims 183-191 is in error because the Examiner has rejected claims directed to "a method of preparation of a pharmaceutical composition which is an *agonist* of a mammalian NPFF receptor". Applicants maintain that this rejection reads on claims 183, 188 and 190 which are drawn to a method of preparation of a pharmaceutical composition which contains a compound which is an agonist of (i.e. a compound that activates) a mammalian NPFF receptor. Applicants point out that claims 184-187, 189 and 191 are drawn to a method of preparation of a pharmaceutical composition which contains a compound that specifically binds to or competitively binds to, and is an antagonist of (i.e. a compound that inhibits binding to) a mammalian NPFF receptor.

Applicants maintain that the disclosure enables all of the claimed methods. That is, one skilled in the art, based on the disclosure, could readily practice the claimed method without undue experimentation.

In response to the first point of the Examiner's rejection, and in

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an attempt to advance prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claims 183-191 to refer to specific NPFF receptors. Accordingly, claims 183-191, as amended, no longer encompass the broad class of mammalian NPFF receptors to which the Examiner objected.

Further in response to the Examiner's rejection, applicants point out that the specification describes three NPFF receptor agonists in Figures 15A-15C. Based on the description on page 28, lines 31-34, an "agonist" is defined as any peptide or non-peptidyl compound which increases the activity of any of the polypeptides of the present invention. Therefore, applicants teach that the key functional characteristic of an NPFF receptor agonist is to increase the activity an NPFF receptor. Clearly, one skilled in the art would recognize that applicants were in possession of more than one NPFF receptor agonist.

Secondly, since applicants *do not claim compounds per se* in their claimed method, it is irrelevant whether one could make such compounds without undue experimentation. Compounds can be readily identified by those skilled in the art by following the testing paradigm taught in the subject specification. Applicants maintain that identifying a compound which has the requisite binding and functional properties is all that is required to practice the invention, and this can be readily accomplished by the skilled practitioner.

Contrary to the Examiner's statement that "...the skilled artisan would have to first generate potential agonists of the NPFF

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receptor, then test for activity", applicants point out that the skilled artisan can readily obtain available compounds, and then test for activity. New compounds need not be made to practice the invention.

Finally, the instant method is not a treatment method. Applicants maintain that the instant method provides a description in the specification for each and every step of the method. Applicants maintain that it is not necessary to limit the claim by indicating a use for the instant composition. In any event, without conceding the correctness of the Examiner's position, applicants have deleted all specific references to pharmaceuticals. The skilled artisan can readily follow the recited steps in order to carry out the invention.

In light of the remarks made hereinabove, applicants maintain that the instant specification enables claims 183-191 as amended. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

In addition, applicants attach hereto as **Exhibit A**, a copy of the ATCC Deposit Receipt for plasmids pWE15-hNPFF1 and pEXJ-rNPFF1 (ATCC Accession No. 203183 and ATCC Accession No. 203184, respectively) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on September 9, 1998; as **Exhibit B**, a copy of the ATCC Deposit Receipt for plasmid pCDNA3.1-hNPFF2b (ATCC Accession No. 203255) indicating that the deposit was made under the terms of the Budapest Treaty on

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the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on September 22, 1998; as **Exhibit C**, a copy of the ATCC Deposit Receipt for plasmid pcDNA3.1-hNPFF1(ATCC Accession No. 203605) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on January 21, 1999.

Under the terms of the deposit, the deposited materials will be maintained for a period of at least 30 years from the date of deposit, or for five years after the most recent request for a sample, whichever period is longer (see ATCC Deposit receipts, Exhibits A-C; 37 C.F.R. §1.806).

In addition, under the terms of the deposit, the deposited materials will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the deposited materials, and ATCC is instructed by the United States Patent and Trademark Office or the depositor to release said materials (see ATCC Deposit receipts, Exhibits A-C; 37 C.F.R. §1.808(a)(1)).

Furthermore, applicants' undersigned attorney states herewith that in accordance with 37 C.F.R. §1.808(a)(2) all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent from the subject application. Where the ATCC cannot furnish samples of the deposits for any reason, applicants shall make a replacement deposit of the material which was originally deposited.

Rejection Under 35 U.S.C. §112, first paragraph

On page 7 of the October 6, 2003 Office Action, the Examiner

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rejected claims 183-191 under 35 U.S.C. §112, first paragraph for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

The Examiner alleged that the claims are drawn to a method of preparation of a pharmaceutical composition which is an agonist of a mammalian NPFF receptor. The Examiner then alleged that the method is not described because i) the specification does not describe the full scope of mammalian NPFF receptors; and ii) the specification does not describe an agonist of the NPFF receptor.

Applicants maintain that the disclosure describes the claimed method. That is, one skilled in the art, based on the disclosure, could conclude that applicants were in possession of the claimed method.

In response to the first point of the Examiner's rejection, and in an attempt to advance prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claims 183-191 to refer to specific NPFF1 receptors. Accordingly, claims 183-191, as amended, no longer encompass the broad class of mammalian NPFF receptors to which the Examiner objected.

Further in response to the Examiner's rejection, applicants point out that the specification describes three NPFF receptor agonists in Figures 15A-15C. Based on the description on page 28, lines 31-34, an "agonist" is defined as any peptide or non-peptidyl compound

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which increases the activity of any of the polypeptides of the present invention. Therefore, applicants teach that the key functional characteristic of an NPFF receptor agonist is to increase the activity an NPFF receptor. Clearly, one skilled in the art would recognize that applicants were in possession of more than one NPFF receptor agonist.

Applicants also draw the Examiner's attention to applicants' arguments with respect to enablement, which also have applicability to the instant written description rejection.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection under 35 U.S.C. §112, second paragraph

On page 8 of the October 6, 2003 Office Action the Examiner rejected claims 184, 186 and 187 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleged that claim 184 is vague and indefinite in the recitation of the term "agonist" in the last line of subsection(a), because the preamble is directed to preparing an antagonist of the NPFF receptor.

The Examiner also alleged that claims 186 and 187 are vague and indefinite because they need to distinguish the compounds more clearly. The Examiner acknowledged that this rejection could be obviated by more clearly labeling the known ligands from the test

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compounds, and clearly setting forth which are to be recovered and made into a pharmaceutical composition.

In response, in an attempt to advance prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claim 184 to correct subsection(a) and claims 186-187 to recite the first and the second chemical compound.

Accordingly, applicants maintain that the amendments obviate the Examiner's rejection.

Summary

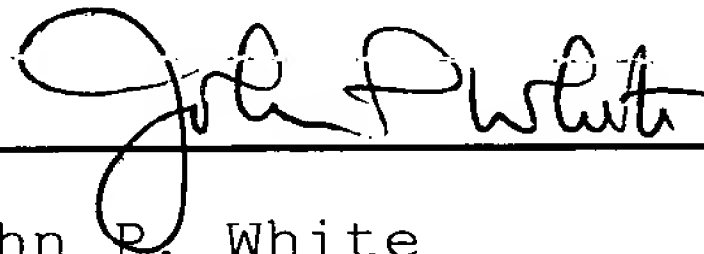
In view of the remarks set forth above, applicants maintain that the claims pending in this application, i.e., claims 183-191 as amended, are in condition for allowance, and allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the enclosed fee of \$110.00, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

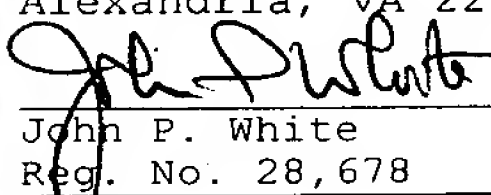
Respectfully submitted,



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